USER MANUAL

EASYPULSE 5

Oxygen Conserving Regulator

1900 SERIES
(CGA 870 Connection)

(198705 shown)

SAVE THESE INSTRUCTIONS

℞ ONLY

Federal (USA) law restricts this device to sale by or on the order of a physician.

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *EasyPulse5* Oxygen Conserving Regulator (Conserver) from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

To regulate high pressure cylinders that provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air they breathe. It is for patients who would normally receive the oxygen via a nasal cannula. The device delivers 100% oxygen at flow settings. It is intended to be used as an oxygen saving device that reduces the drying of the airways.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a user to install and operate the Oxygen Conserving Regulator (Conserver). This is provided for your safety and to prevent damage to the Conserver. If you do not understand this manual, DO NOT USE the Conserver and contact your Provider.

⚠ DANGER

This product is not intended as a life-sustaining or life-supporting device.

EXPLANATION OF ABBREVIATIONS

kPa	Kilopascal
psi	Pounds Per Square Inch
l/min	Liters Per Minute
b/min	Breaths Per Minute

SAFETY INFORMATION - WARNINGS AND CAUTIONS

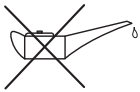
⚠DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS



Symbol for “USE NO OIL”

Symbol for “NO SMOKING”

Symbol for “COVERING DEVICE WITH GARMENTS WILL PRODUCE OXYGEN ENRICHED ATMOSPHERE”

CE
0473

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

⚠WARNING

- **ALWAYS** confirm prescribed dose before administering to patient and monitor on a frequent basis.
- Always follow ANSI and CGA standards for Medical Gas Products and Oxygen Handling (G-4).
- Keep cylinder valve closed at all times when cylinder is not in use.
- NO OXYGEN is delivered when the pointer ▽ is aligned with "OFF", or between settings.
- This Conserver is not to be used by patients who breathe through their mouths.
- **DO NOT** use if dirt or contaminants are present on or around cylinder, valve, product or connecting devices.
- **DO NOT** use oils, greases, organic lubricants or any combustible materials on or near this product. Wash and dry hands properly prior to usage.
- **DO NOT** use a humidifier with the Conserver.
- **DO NOT** allow cylinders to tip or fall. Secure gas cylinders so they cannot fall. For optimum safety keep cylinder upright whenever possible.
- **DO NOT** store cylinders near sources of heat or flame.
- **DO NOT** use while sleeping without consulting your Provider.
- **DO NOT** smoke in an area where oxygen is being administered.
- **DO NOT** use near any type of flame or flammable/explosive substances.
- Use only USP grade medical oxygen.
- The Conserver is equipped with a relief valve. If you hear a loud hissing or popping sound coming from the product, discontinue use of product, close cylinder valve, and contact your Provider.
- The Conserver is designed to operate with a single lumen, adult cannula with a maximum length of 7 feet (2.1 m).
- The cannula is for single patient use only.

⚠CAUTION

- Only personnel instructed and trained in its use should operate the Conserver.
- The Conserver contains magnetic, ferrous material that may affect the results of an MRI.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with Ethylene Oxide.
- **DO NOT** clean with aromatic hydrocarbons.
- Store the Conserver in a clean area when not in use.
- Avoid dropping the Conserver or placing it in a position where it could fall and become damaged.
- Consistent with the recommendations of the medical community on the use of conserving devices, it is recommended that the Oxygen Conserving Regulator be qualified on patients in the situations it will be used.
- The Conserver may not be able to detect all respiratory efforts of the patient. (Shallow breathers may not be able to trigger the Conserver.)
- Operating the Conserver outside its range of operating conditions may affect its accuracy and performance.

PRINCIPLES OF OPERATION

The Oxygen Conserver is designed to be used with high-pressure oxygen systems. It consists of a cylinder connection, cylinder contents gauge (if equipped), high-to-low pressure regulator, orifice plate and a conserving demand module. The regulator reduces the high pressure of the cylinder to the working pressure of the orifice plate. The orifice plate uses calibrated orifices to deliver a selected flow to the conserving demand module. The conserving demand module controls the pulse size and timing to the patient. It supplies a pulse of oxygen at the beginning of each breath. This reduces the oxygen demand on the system and limits the drying of the airways. The flow is determined by setting the flow control knob to the prescribed flow. The oxygen is supplied to the patient through the cannula.

SPECIFICATIONS

Inlet Pressure Range: 300 - 3000 psi (2068 - 20684 kPa)

Pressure Gauge Accuracy: 3 - 2 - 3% of full scale

Dimensions: (Are approximate and may vary by model)

Model: 198705

Weight:	9.9 oz	(279 g)
Overall Length:	4.75 in	(12.07 cm)
Width:	2.63 in	(6.67 cm)
Height:	2.50 in	(6.35 cm)

Pulse Settings: 1, 2, 3, 4, & 5 l/min Equivalents

Flow Settings: 2 l/min Continuous (198705)
1 through 6 l/min Continuous (198712)

Accuracy: Continuous Settings: within ± 10%

PULSE ONLY		
	Accuracy: Pulse Settings:	Within +/- 15% of the nominal bolus value (at each breath rate)
	Savings Ratio:	Up to 5.7:1
	Trigger Method:	Inspiratory effort (Negative pressure from patient inhalation)
	Breathing Frequency:	Up to 35 b/min

Cannula Requirement: Maximum 7 foot (2.1 m) long standard adult single lumen nasal cannula.

Operating Conditions:

Temperature:	35°F to 105°F (1.7°C to 40.6°C)
Altitude:	Sea level to 10,000 ft (0 to 3,048 m)

Storage Conditions:

Temperature:	-40°F to 140°F (-40°C to 60°C)
Maximum Humidity:	95% Noncondensing

Oxygen Cylinder Connection: CGA 870 Valve

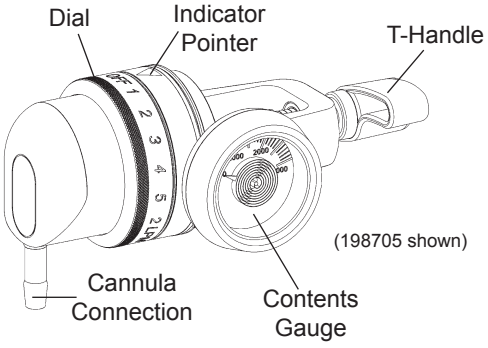
Ignition and Fault Tolerance: Meets ASTM G175-03

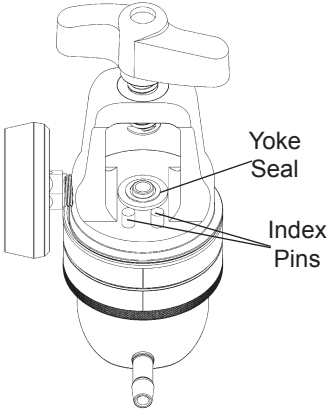
Specifications are subject to change without prior notice. Manuals available on our Website; www.precisionmedical.com

COMPONENT DESCRIPTION

⚠CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.





INSTALLATION

⚠WARNING

- Read this User Manual before installing or operating the Oxygen Conserving Regulator.
- Inspect the Conserver and cylinder valve to ensure they are free of oils, greases or other contaminants.
- **DO NOT** direct flow of oxygen at any person, or flammable material when cracking open the cylinder.
- **DO NOT** use without yoke seal.
- **DO NOT** use plastic yoke seals.
- Use Precision Medical, Inc. yoke seal made of viton and brass.
- The yoke seal supplied with the Conserver is reusable.

CAUTION

- Inspect the Oxygen Conserving Regulator for visual damage before use, DO NOT USE if damaged.
- **DO NOT** use tools to tighten T-handle, this can lead to over tightening and will cause damage to the Conserver.
- Be sure all connections are tight and leak free.
- **DO NOT** use liquid leak detector to test for leaks.

NOTE: For operational instructions on how to operate the cylinder consult your Provider.

1. Position the cylinder so the oxygen cylinder valve outlet is pointing away from the user and any other person(s).
2. Before installing the Conserver, “crack” cylinder valve by opening the valve slightly to remove any foreign particles and then close valve.
3. Be sure the Conserver is in the “OFF” position. Align “OFF” with the indicating pointer ▽.
4. Be sure the CGA 870 connection high pressure inlet has a yoke seal.
5. Align Index Pins with Index Pin Alignment Holes in Post Valve.
6. Hand tighten T-handle until snug.

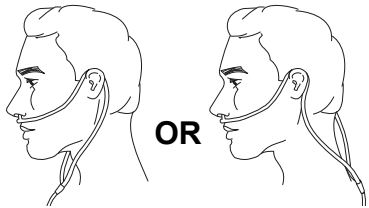
OPERATING INSTRUCTIONS

1. Attach a **standard adult single lumen oxygen nasal cannula**, no longer than 7 feet (2.1 m) to the Conserver's outlet according to the cannula manufacturer's instructions.

⚠CAUTION

- **DO NOT** use pediatric, low flow nasal cannulas or oxygen masks with the Conserver.
- **DO NOT** block the cannula connection or kink cannula tubing when the Conserver is in use, this may damage the Conserver.

2. Place the cannula over your ears and position the prongs in your nose as instructed by your Provider or cannula manufacturer.



3. Slowly open cylinder valve counterclockwise, until completely open.
4. Turn dial on the Conserver until indicating pointer ▽ is aligned with the prescribed setting.
5. Breathe through your nose.

NOTE: • When on a pulse setting, there is flow or a pulse only at the beginning of each breath. If you do not feel the pulse at the beginning of each breath, check the setting. If there is still no pulse, turn dial to an equivalent "Continuous" setting.

• Because each patient's breathing pattern is different and the environment varies, it may be difficult to feel some low setting pulses.

6. To remove the Conserver from cylinder:
   - **Completely close oxygen cylinder valve.**
   - Turn the Conserver dial to any “Continuous” position.
   - Wait for oxygen to stop flowing from Conserver.
   - Remove the Conserver from cylinder valve.
   - **DO NOT** try to loosen T-handle beyond stop. Damage to the Conserver will occur.

⚠ DANGER

NEVER attempt to remove the Conserver from a cylinder unless the cylinder valve is closed.

⚠ WARNING

- When pointer on contents gauge enters red zone, (500 psi (3447 kPa) and below), it is recommended to change to a full oxygen cylinder.
- NO OXYGEN is delivered in between settings.

To avoid injury to patient:

- **ALWAYS** confirm prescribed setting before administering to patient and monitor flow on a frequent basis.

⚠ WARNING

- Use only Precision Medical, Inc. carry bag designed for the *EasyPulse5* to prevent an oxygen enriched environment.
- **DO NOT** place the unit under clothing while in use. When the Conserver is in use, a small amount of oxygen is vented. Wearing the unit under clothing may saturate fabrics with oxygen and cause them to burn rapidly, if exposed to sparks or flame. It may take several hours for oxygen levels in fabrics to return to normal.
- **ALWAYS** insert cylinder and Conserver into bag, cylinder first with gauge facing mesh. Reference accessory photo, (pg. 13).

MAINTENANCE / CLEANING

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Conserver with a cloth dampened with mild detergent and water.
3. Wipe dry with a clean cloth.
4. Store the Conserver in a clean area free of grease, oil, and other sources of contamination.

CAUTION

- **DO NOT** use cleaning solutions.
- **DO NOT** immerse the Conserver in any kind of liquid.
- **DO NOT** attempt to repair the *EasyPulse5* Oxygen Conserving Regulator.
- All repairs must be performed by Precision Medical, Inc. or Authorized Representative.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

DISPOSAL INSTRUCTIONS

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing the device and/or its packaging.

Please Recycle

TROUBLESHOOTING

If the Conserver fails to function, consult the Troubleshooting Guide below. If problem cannot be solved, consult your Provider.

TROUBLESHOOTING GUIDE

Problem	Probable Cause	Remedy
No flow	1. Cylinder valve closed 2. Conserver in “OFF” position 3. Cylinder empty 4. Dial not set at proper position 5. Conserver not sensing breath	1. Open the valve on cylinder 2. Set to prescribed setting 3. Replace cylinder 4. Set dial so indicator points to a setting 5. Check position of cannula in nose, DO NOT breathe through mouth
Leaking at cylinder connection	1. Missing or defective yoke seal 2. Defective cylinder valve	1. Replace with Precision Medical yoke seal 2. Contact your Provider

REPLACEMENT PARTS

Description	Part #
Cannula	504833
Yoke Seal	1221

ACCESSORIES

Description	Part #
Carry Bag M6	503920
Carry Bag M4/M6	504184
Carry Bag ML6/ML9	504185

Carry Bag with shoulder strap

Conserver properly installed in Carry Bag

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Easy Pulse Oxygen Conserving Regulator (the Product) will be free of defects in workmanship and/or material for the following periods:

Two (2) years from date of shipment.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

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REF

EasyPulse 5 Oxygen Conserving Device)
198705EN, 195405, 19DE05, 19ES05, 19ES05-EN, 19GB05, 19ES05, 19SE05-ES, 198705NG, 195405NG, 19ES05NG, 19ES05NG-EN, 19GB05NG, 19SE05NG, 19SE05NG-NO, 19WM0501

Classification: IIb
Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD
We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC on medical devices.
We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.
Applied Standards: BS 341-3, DIN 477-1, EN 837-1, EN1041, EN ISO 14971, EN ISO 15001, ISO 228-1, ISO 15223-1, ISO 10524-1, ISO 10524-3, ISO 18779, SS 367615

Notified Body: Intertek AMTAC Certification Services Limited CE 0473
Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's: 1126 CE
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Devices already manufactured: S/N traceability Device History Records
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Position: Quality Systems/ISO Representative
Date of Issue: 04 August 2012

Tell us how we are doing!
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